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Interfaith Center on Corporate Responsibility

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Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061, (HFA-305)
Rockville, MD 20852.

Dear FDA:

Docket No. 02D-0325

We, the International Health & Tobacco Steering Committee of Interfaith Center on Corporate Responsibility write to urge you, the Food and Drug Administration, to support your own Public Health Notification on the plasticizer di-(2-ethylhexyl) phthalate (DEHP) in medical devices, with policies that will enable providers to implement its recommendations. In particular, we urge the FDA to require labeling of medical devices containing DEHP. Our comments are offered in response to the "Draft Guidance for Industry and FDA on Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2-Ethylhexyl)phthalate (DEHP)" recently released for comment by your agency.

Interfaith Center on Corporate Responsibility is a North American association of over 275 Protestant, Roman Catholic and Jewish institutional investors, including denominations, religious communities, pension funds, dioceses, foundations, publishing companies and health care corporations. The combined assets of the members exceed $100 billion. ICCR members address issues of corporate responsibility through their resources, particularly their investments. Since 1998, members have been asking health care related corporations in which they hold investments, to phase out the manufacture or the use of PVC-containing or phthalate-containing medical supplies where safe alternatives are available. We have made this request to 9 different corporations because large quantities of phthalates are used to manufacture flexible PVC medical products and often the plasticizer that is used is DEHP. Most of the corporations have articulated an awareness of the problem with DEHP and PVC. Several are taking measures to move away from these substances in their products or in the use of such products.

The National Toxicology Program review and the FDA's own Safety Assessment have found that exposure to DEHP during early stages of development may be harmful to the developing male reproductive system. That concern was identified at levels of exposure expected to occur during some routine uses of medical devices. High-risk groups include male fetuses, neonates, and peri-pubertal males.

In its recent Public Health Notification, the FDA identified several procedures that pose the highest risk of exposure to DEHP: exchange transfusions in neonates; ECMO in neonates; total parenteral nutrition (TPN) in neonates (with lipids in the bag); enteral nutrition in neonates and adults; aggregate doses in patients receiving heart transplant or undergoing coronary artery bypass graft surgery; massive infusion of blood into trauma patients; and transfusion in adults undergoing ECMO. The Public Health Notification

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further recommends considering alternatives to DEHP-containing devices when high-risk procedures are to be performed on male neonates, pregnant women who are carrying male fetuses, and peri-pubertal males.

In its draft Guidance subsequently released to the public, the FDA identified a list of device categories regulated by its Center for Devices and Radiological Health that may contain PVC components and therefore the plasticizer DEHP. Currently, there are only a handful of devices that are labeled.

The Guidance recommends that manufacturers consider the feasibility of replacing PVC containing DEHP with either alternative materials for plasticizers, or using coatings that may minimize patient exposure to DEHP. If manufacturers choose not to redesign or reformulate their DEHP-containing products, the FDA recommends, but does not require, that manufacturers label their products so that users will be able to identify those products that contain DEHP.

This voluntary approach does not provide assurance that devices will be labeled, nor that practitioners will have enough information to make informed decisions. If manufacturers choose not to label their DEHP-containing products, medical device users would be left in the dangerous position of not knowing whether or not they were using a DEHP-containing product, making protection of vulnerable patients very difficult. Our dialogues with corporations lead us to believe that without an FDA requirement, many manufacturers will not notify consumers of the presence of DEHP in medical devices. Additionally, obtaining information from manufacturers as to whether or not a product contains DEHP is not always an easy task.

The information already published by the FDA regarding the potential harm of DEHP appears to meet the FDA's definition of when a label should be required - that is, when usage by or affecting children may be harmful to health. The population affected by the needed labeling is not insignificant. Pregnant women, women who may be pregnant, peripubertal males, and neonates constitute a large patient population at risk from DEHP exposure.

We urge the FDA to formulate policies that allow practitioners to implement the Public Health Notification issued by your agency. Without labeling, it is difficult to understand how practitioners are to carry out the FDA recommendations. We urge the FDA to give them the tools they need to protect the health of patients.

We also believe that suppliers and distributors should be encouraged to make information about DEHP and/or PVC readily available in catalogs and other materials used in the marketing of medical devices. Without this information, purchasers and health care providers will not be able to make informed purchasing decisions necessary for protecting the health of patients.

Thank you for consideration of our position.

Sincerely,

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